

**REMARKS**

Applicant submits this Amendment in response to an Office Action mailed by the USPTO on November 19, 2003.

In the Office Action, the Examiner has rejected claims 9-11, 13-17 and 19-20 under 35 U.S.C. §102(b) as anticipated by Japanese Publication No. JP 11152355 A to Mitsui. Applicant respectfully traverses that rejection.

Matsui discloses a steam or hot water sterilization process for an annular olefin system resin plastic solid. The disclosed process can sterilize an annular olefin system resin plastic solid using steam or hot water without cloudiness or milkiness of the olefin plastic. Matsui discloses certain temperatures and relative humidity parameters, but, applicant respectfully submits, does not teach or suggest each step recited by applicant's claims, as is required of a proper §102 reference. Specifically, and with regard to applicant's claim 9, applicant submits that Matsui does not disclose a step of reducing the temperature of said syringe assembly to a second temperature of between 80° C and less than 100° C and maintaining said second temperature for at least 20 minutes. Applicant respectfully submits that the disclosure of Matsui identified by the Examiner as providing such teaching (i.e., page 7, technical field, lines 55-61) teaches a processing temperature of 80 degrees C or more, not a temperature between 80° C and less than 100° C, as recited by applicant's claim 9. Applicant respectfully submits that Matsui fails to teach or suggest each limitation recited by claim 9, and thus is not a proper §102 reference.

Claims 10-13 depend, directly or indirectly from claim 9. For the reasons set forth above with regard to the deficiencies in the teaching of Matsui, applicant respectfully submits that claims 10-13 are also not anticipated by Matsui.

With regard to claim 14, applicant respectfully submits that Matsui once again fails to teach or suggest each limitation recited by that claim, and is thus not a proper §102 reference. More specifically, Matsui does not teach or suggest reducing the humidity of said cyclic olefin container or delivery device and maintaining a second temperature less than 120° C, as recited by claim 14. In contrast, and respectfully, contrary to the Examiner's position, Matsui does not disclose reducing the humidity, as recited by applicant's claim. Matsui merely discloses providing an atmosphere of 50% or less of relative humidity. Matsui is silent as to any change in the relative humidity, such as a reduction as recited by applicant's claim 14. In addition, Matsui does not disclose maintaining a second temperature less than 120° C, as recited by applicant's claim. Rather, as discussed above, Matsui merely discloses a processing temperature of 80 degrees C or more. Applicant respectfully submits that such a teaching does not anticipate claim 14, which includes the limitation that the second temperature be less than 120° C. Applicant respectfully submits that Matsui fails to teach or suggest each limitation recited by claim 14, and thus is not a proper §102 reference.

Claims 15-17 and 19-20 depend, directly or indirectly from claim 14. For the reasons set forth above with regard to the deficiencies in the teaching of Matsui, applicant respectfully submits that claims 15-17 and 19-20 are also not anticipated by Matsui.

The Examiner also rejected claims 1-8, 12 and 18 under 35 U.S.C. §103(a) as unpatentable over Matsui in view of U.S. Patent No. 5,207,983 to Liebert et al. Applicant respectfully traverses that rejection.

Liebert et al. is directed to a process for terminal sterilization of pre-filled plastic and glass syringes. The Examiner has taken the position that Matsui teaches all limitations of claim 1, except for the step of maintaining the first temperature for at least 30 minutes. The Examiner maintains that Liebert et al. teaches that limitation and, in combination with Matsui, renders the invention recited by applicant's claim 1 obvious. The disclosure of Liebert et al. to which the Examiner points to account for the deficiency of Matsui is column 1, lines 30-36. Applicant respectfully submits that the disclosure of Liebert et al. is directed to a different processing step than recited by applicant's claim 1. More specifically, applicant claims a method comprising, *inter alia*, a step of first heating said cyclic olefin component to a first temperature greater than 100°C in the presence of steam for at least 30 minutes to sterilize said cyclic olefin component. However, Liebert et al, at column 1, lines 30-36, discloses "purging air from the autoclave chamber by forcing saturated steam therethrough...for about a minute to 30 minutes." The disclosure of Liebert et al. is directed to a processing step that is performed prior to the step of heating the autoclave chamber (i.e., prior to the sterilization step(s)). See, e.g., Liebert et al, column 1, lines 30-38, "[T]he process of steam-sterilization...include[s]...further introducing steam into the autoclave chamber so that the temperature of about 100°C. to 125° C. is reached therein." Thus, Liebert et al. merely teaches air purging for a period of about 30 minutes. Liebert et al. does not teach or suggest applicant's claimed first heating step of at least 30

minutes. Thus, applicant respectfully submits that the Examiner's proposed combination of Matsui and Liebert et al. does not render the invention recited by claim 1 obvious.

With regard to claims 2-3 and 5-8, the teachings of Liebert et al. do not overcome the deficiencies of Matsui, as identified above and discussed in connection with claims 9 and 14. Thus, applicant further respectfully submits that the Examiner's proposed combination of Matsui and Liebert et al. does not render the invention recited by claims 2-3 and 5-8 obvious.

Finally, with regard to claims 4, 12 and 18, once again the teachings of Liebert et al. fail to overcome the deficiencies of Matsui, as identified above and discussed in connection with claims 9 and 14. Thus, applicant further respectfully submits that the Examiner's proposed combination of Matsui and Liebert et al. does not render the invention recited by claims 4, 12 and 18 obvious.

Thus, in view of the distinguishing points set forth above, applicants respectfully submit that their invention, as recited by the claims of the present application, is patentable over Matsui and Liebert et al., or any other prior art reference of record in the present application, whether considered alone or in any hypothetical combination. Applicants further respectfully submit that the Examiner's rejections of the claims is no longer tenable, and applicant respectfully requests withdrawal of those rejections.

Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Amendment and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Application No.: 09/849,090  
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Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

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